510(k) SUMMARY

1. Submitter's identification

a. MORIA S.A.
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b. Contact person: Mélanie RENAUD-SAMIRI
QA & Regulatory Affairs Manager
E mail: mrenaud@moria-int. com

c. Date Summary Prepared: July 2nd, 2002

2. Device name

Trade Name: M2 SINGLE USE microkeratome

3. Classification name

Keratome (per CFR 886.4370)

4. Substantial equivalence

Substantial equivalence is being claimed to the following legally marketed devices:

Device name: **CARRIAZO BARRAQUER SINGLE USE Microkeratome**
Company name: **MORIA S.A.**
Document control number:**K003594**

And

Device name: **CARRIAZO BARRAQUER II Microkeratome**
Company name: **MORIA S.A.**
Document control number:**K002191**

5. Device description

List of components

a) Power unit
b) Motor
c) Suction rings
d) Applanator lenses
e) Footswitches
f) Keratome head with pre-inserted Keratome blade

a) Power unit

The power unit used for the M2 SINGLE USE microkeratome is the same as the power unit used for the predicate devices CARRIAZO BARRAQUER SINGLE USE Microkeratome (K003594) & CARRIAZO BARRAQUER II Microkeratome (K002191) already legally marketed in the USA by our company.

The power unit includes pumps for producing vacuum.
The power unit has been designed to operate the Keratome by means of electric motor or by means of a gas turbine motor.

Only one of the above power options can be selected at the time by means of a 2 position switches in the front panel.

The front panel has several displays and features:

- Vacuum pressure gauge,
- Gas pressure gauge,
- Battery level indicator,
- Battery charge indicator,
- Connectors:
  - DC motor outlet,
  - Gas outlet,
  - Vacuum outlet,

The back panel has several displays and features:

- Connectors:
  - Gas inlet,
  - Foot pedals,
  - Battery charger.

All connectors are of different type for preventing connecting mistakes.

b) Keratome motor

Option 1: Turbine motor

The turbine motor is gas powered. The recommended gas is medical grade nitrogen. The turbine has been marketed by MORIA since six years (see predicate device PLANCON MICROLAMELLAR KERATOME K970377).

Option 2: The electrical motor

The drive system has two built-in electrical motors (one motor for the blade oscillation and one motor for the advance of the microkeratome).

c) Keratome head

The Keratome head includes the blade that is moved by the motor.

Different heads are available in order to adjust the thickness of the cut.

d) Suction rings

The suction rings are used to fixate and pressurize the eye and provide a base for the microkeratome.

e) Applanator lenses

The applanator lenses are made of clear methylmethacrylate with a stainless steel handle.

They are used with the rings to control disk diameter before the cut.

The upper face is convex for magnification.

The base face (contact face) is plane, with an engraved and calibrated reticule diameter.

f) Keratome blade

The blade is made of two parts: the blade edge in low carbon steel, and the blade holder, which is not in contact with the patient's eye.

6. Statement of intended use

The M2 SINGLE USE microkeratome is intended for use in making of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

7. Discussion of tests and results

Keratomes have been used for lamellar keratoplasty for more than 30 years.

In-vitro studies on porcine eyes demonstrated:

- The flap thickness consistency,
- The safety of corneal resections,
- The good quality of corneal resections.

In-vivo studies on 72 human eyes showed that the M2 SINGLE USE microkeratome is a safe Keratome able to create, equivalently to the predicate device, circular lamellar resection of a predetermined diameter and thickness and bed smoothness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2002

MORIA S.A.
c/o Mrs. Melanie Renaud-Samiri
Quality Assurance & Regulatory Affairs Manager
15, Rue Georges Besse
92160 Antony
France

Re: K022560
Trade/Device Name: M2 Single Use microkeratome
Regulation Number: 886.4370
Regulation Name: Keratome
Regulatory Class: I
Product Code: HMY
Dated: July 2, 2002
Received: August 2, 2002

Dear Mrs. Renaud-Samiri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known):

Device Name:

M2 SINGLE USE microkeratome

Indications for use:

The M2 SINGLE USE microkeratome is intended for use in the making of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K022560

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use ___ (Optional Format 1-2-96)